

COOPERATION AGREEMENT

dated July 2013

Between

**The International Health Terminology Standards
Development Organisation
(IHTSDO)**

and

**The Regenstrief Institute, Incorporated
(RII)**

**MILBANK, TWEED, HADLEY & M^cCLOY LLP
London**

Table of Contents

Clause	Page
1. Definitions and Interpretation	3
2. Parties' General Rights and Obligations.....	3
3. Cooperative Works & Cooperative Areas	4
4. Intellectual Property Rights	4
5. Performing the Cooperative Works	10
6. Translations.....	10
7. Non-Duplication	11
8. Endorsement	11
9. Governance and Approvals.....	12
10. Annual Work Plan Process	13
11. Term of the Agreement.....	14
12. Termination.....	14
13. Representations and Warranties.....	15
14. Limitations of Liability	16
15. Confidentiality	16
16. Miscellaneous Provisions.....	18
17. Governing Law and Jurisdiction.....	22
SCHEDULE 1 DEFINITIONS AND INTERPRETATION	25
SCHEDULE 2 COOPERATIVE WORKS AND METHODS	31
SCHEDULE 3 ESSENTIAL ASPECTS OF LOINC AND SNOMED CT	42

THIS AGREEMENT is made on July 2013

BETWEEN:

- (1) **THE INTERNATIONAL HEALTH TERMINOLOGY STANDARDS DEVELOPMENT ORGANISATION** (*forening med begrænset ansvar*), an association (*foreningen*) established under the laws of Denmark (CVR No. 30363434), whose principal place of business is at Gammeltorv 4, 1. sal, DK-1457 Copenhagen K, Denmark (“**IHTSDO**”); and
- (2) **THE REGENSTRIEF INSTITUTE, INCORPORATED**, a non-profit corporation established under the laws of the state of Indiana, USA, whose principal place of business is at 1050 Wishard Blvd., 6th Floor RHC, Indianapolis, IN 46202 (“**RII**”).

In this Agreement, IHTSDO and RII are collectively referred to as the “**Parties**”, and each of them is referred to as a “**Party**”.

INTRODUCTION:

- (A) RII owns the Intellectual Property Rights in, and maintains, LOINC. RII develops and disseminates LOINC for the benefit of users who share, aggregate, and process clinical data.
- (B) IHTSDO owns the Intellectual Property Rights in, and maintains, SNOMED CT. IHTSDO develops and disseminates SNOMED CT for the benefit of its members and other users of SNOMED CT.
- (C) The Parties wish to support enhanced clinical system safety, functionality and interoperability by establishing principled relationships between SNOMED CT and LOINC.
- (D) The Parties also wish to provide effective support for providers and users who implement different combinations of SNOMED CT and LOINC in health information systems.
- (E) The purpose of this Agreement is to establish a suitable mechanism for collaboration between the Parties that allows the Parties to: (i) address coding and modelling of terminology content in the domains covered by LOINC orders and observations; (ii) support consistent coding of order entry and result reporting; (iii) reduce duplication of effort; (iv) achieve the objectives set out in this Introduction; and (v) provide for the future development of the Parties’ respective works of nomenclature.
- (F) The Parties intend that, through this collaboration, they shall define areas of responsibility for the Parties and establish sustainable mechanisms that allow the Parties to exchange, map and harmonise specific elements of LOINC and SNOMED CT and to

support the endorsement of both LOINC and SNOMED CT to promote their uptake and use.

THE PARTIES AGREE as follows:

1. DEFINITIONS AND INTERPRETATION

- 1.1 In this Agreement, capitalised words and phrases shall have the meanings given in paragraph 1 of Schedule 1 (*Definitions and Interpretation*) to this Agreement.
- 1.2 This Agreement shall be construed in accordance with paragraph 2 of Schedule 1 (*Definitions and Interpretation*) to this Agreement.
- 1.3 If there is any conflict or inconsistency between Schedule 2 (*Co-operative Works and Methods*) and any other provision of this Agreement, the other provision of this Agreement shall take precedence (but only to the extent of the conflict or inconsistency).

2. PARTIES' GENERAL RIGHTS AND OBLIGATIONS

2.1 Freedom to enter into other arrangements

- 2.1.1 Nothing in this Agreement shall prevent either Party from entering into any agreement or arrangement with any third party.
- 2.1.2 Nothing in this Agreement shall affect any pre-existing rights of IHTSDO in respect of SNOMED CT, or any pre-existing rights of RII in respect of LOINC.

2.2 Approvals

- 2.2.1 In this Agreement, the agreement to any matter by IHTSDO or the Management Board of IHTSDO shall require an agreement in writing signed by both the Chair of the Management Board of IHTSDO and the Chief Executive Officer of IHTSDO.
- 2.2.2 In this Agreement, the agreement to any matter by RII shall require an agreement in writing signed by both the Associate Director of Terminology Services and the Director of the Regenstrief Center for Biomedical Informatics.

2.3 Editorial control

- 2.3.1 The Parties shall retain editorial control of their respective terminologies and nothing in this Agreement obliges either Party to make additions of any specific content to its respective works of nomenclature.

3. **COOPERATIVE WORKS & COOPERATIVE AREAS**

- 3.1.1 The Parties shall cooperate to produce the Maps, content additions and Expression Associations in the manner set out in Schedule 2 (the “**Cooperative Work**”). Maps and Expression Associations shall include an indication of the original source of the component (LOINC, SNOMED CT, or both) as described in paragraph 7 of Schedule 2.
- 3.1.2 The Parties shall carry out the Cooperative Work only in relation to the following areas (the “**Cooperative Areas**”):
- (a) Laboratory, including discrete orders and observations and panel names for orders (excluding panel structure);
 - (b) Anthropomorphic measurements and evaluations; and
 - (c) Vital signs and physiological measurements.
- 3.1.3 As the Parties carry out the Cooperative Work in this Agreement, three categories of intellectual property will be generated: Jointly Owned New Works, New IHTSDO IPR, and New RII IPR. The Intellectual Property Rights (IPR) relative to the Cooperative Work are addressed in clause 4.

4. **INTELLECTUAL PROPERTY RIGHTS**

4.1 **Pre-existing Intellectual Property Rights**

- 4.1.1 This Agreement shall not assign or otherwise transfer any Intellectual Property Rights of either Party:
- (a) existing as at the Effective Date; or
 - (b) created during the Term of this Agreement, other than as set out in this clause 4 in respect of the New IHTSDO IPR, the New RII IPR and the Jointly Owned New Works.

4.2 **Licenses granted to support the Cooperative Work:**

- 4.2.1 IHTSDO grants to RII a worldwide, royalty-free, irrevocable and non-transferrable licence for the Term of this Agreement, to use, load, execute, store, transmit, display, copy, and create excerpts from the International Release of SNOMED CT, for internal purposes only and solely for the purpose of carrying out the activities and carrying out the Cooperative Work in accordance with Schedule 2 of this Agreement.

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- 4.2.2 RII's rights and obligations in respect of SNOMED CT content for any purpose other than as expressly contemplated under this Agreement, shall be governed by the standard IHTSDO Affiliate Licence.
- 4.2.3 RII grants to IHTSDO a worldwide, royalty-free, irrevocable and non-transferrable licence for the Term of this Agreement, to use, load, execute, store, transmit, display, copy, and create excerpts from LOINC, for internal purposes only and solely for the purpose of carrying out the activities and carrying out the Cooperative Work in accordance with Schedule 2 of this Agreement.
- 4.2.4 IHTSDO's rights and obligations in respect of LOINC content for any purpose other than as expressly contemplated under this Agreement, shall be governed by the LOINC Copyright Notice and License (available at <http://loinc.org/terms-of-use>).
- 4.3 **Jointly Owned New Works**
- 4.3.1 In performing the Cooperative Work in relation to the Cooperative Areas, the Parties will produce Maps and Expression Associations in accordance with the process in Schedule 2 (the "**Jointly Owned New Works**").
- 4.3.2 The Parties shall jointly own the Intellectual Property Rights in the Jointly Owned New Works, provided that neither Party may use, load, execute, store, transmit, display, copy, modify, amend, decompile, create derivative works of, distribute, or publish the Jointly Owned New Works without the prior written consent of the other Party unless such activities are permitted under clause 4.3.3.
- 4.3.3 Either Party may, without obligation to compensate the other Party (i) use, load, execute, store, transmit, display, copy, modify, amend and decompile the Jointly Owned New Works for the Party's internal purposes only, and (ii) distribute and publish the Jointly Owned New Works in that Party's customary release format, provided that distribution and publication of the Jointly Owned New Works by the IHTSDO shall be only as part of the International Release of SNOMED CT, and distribution and publication of the Jointly Owned New Works by RII shall be only as part of the LOINC Release.
- 4.3.4 The licence granted under clause 4.3.3:
- (a) is perpetual and may not be revoked at any time or for any reason whatsoever, including any breach of this Agreement (however serious) by the licensee or the termination of this Agreement;
 - (b) is transferable only in accordance with clause 16.2 and 16.3;

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- (c) includes the right to grant sub-licences through an unlimited number of tiers of sublicensees; and
 - (d) is subject to the licensee complying with the licensor's policies on the use of its trade marks.

4.3.5 RII shall include the following acknowledgement on their website and in the Release Files containing the Jointly Owned New Works: "This material includes content from SNOMED Clinical Terms (SNOMED CT[®]) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights are reserved. SNOMED CT[®] was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of the IHTSDO".

4.3.6 IHTSDO shall include the following acknowledgement on their website and in the Release Files containing the Jointly Owned New Works: "This material contains content from LOINC[®] (<http://loinc.org>) that is used by permission from the Regenstrief Institute. The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2013, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available in perpetuity at no cost under the license at <http://loinc.org/terms-of-use>."

4.4 **New IHTSDO IPR**

4.4.1 RII grants the IHTSDO a worldwide, royalty-free licence to:

- (a) incorporate LOINC Allowable Content, and any Spanish language translations of LOINC Allowable Content, into SNOMED CT;
- (b) modify the LOINC Allowable Content, and any Spanish language translations of LOINC Allowable Content, to the extent necessary to adapt the LOINC Allowable Content and Spanish language translations of LOINC Allowable Content to standard SNOMED CT distribution formats; and
- (c) use, load, execute, store, transmit, display, copy, distribute and publish all LOINC Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.4.1(a)-(b) above, incorporated into SNOMED CT in accordance with this Agreement,

provided that any such LOINC Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.4.1(a)-(b) above, may be distributed and published by IHTSDO only as an integral part of SNOMED CT (and not as a standalone work).

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- 4.4.2 In performing the Cooperative Work in relation to the Cooperative Areas, the Parties will produce content additions or modifications to SNOMED CT as a result of incorporating the LOINC Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.4.1(a)-4.4.1(b) above (the “**New IHTSDO Content**”).
- 4.4.3 Subject to clause 4.1.1, IHTSDO shall own all right, title and interest in and to all Intellectual Property Rights in the New IHTSDO Content and any Intellectual Property Rights in the selection, arrangement or compilation of LOINC Allowable Content, or translations thereof, as incorporated within SNOMED CT, the Intellectual Property Right referred to in this Clause 4.4.3 being the “**New IHTSDO IPR**”. Nothing in this clause 4.4 shall affect RII’s underlying Intellectual Property Rights in and to LOINC.
- 4.4.4 RII shall not, and shall procure that no person acting on its behalf shall, register or attempt to register any of the New IHTSDO IPR or any right, title or interest in or to it.
- 4.4.5 RII:
- (a) assigns to IHTSDO (by way of present assignment of future Intellectual Property Rights) all of its right, title and interest in and to the New IHTSDO IPR; and
 - (b) shall procure that each person acting on behalf of RII under or in connection with this Agreement assigns to RII all of his or her right, title and interest in and to the New IHTSDO IPR on terms that entitle RII to assign the New IHTSDO IPR to IHTSDO pursuant to clause 4.4.5(a) above.
- 4.4.6 In so far as clause 4.4.5 assigns any right, title or interest in or to any Intellectual Property Rights, the assignment shall include all rights and benefits relating to the assigned Intellectual Property Rights, including the right to sue for damages and to claim any other remedy or relief in respect of any infringement or unauthorised use of those Intellectual Property Rights that occurred before the date of the assignment.
- 4.4.7 RII shall procure that every author of the New IHTSDO IPR (or any part of the New IHTSDO IPR) acting on its behalf irrevocably and unconditionally waives all moral rights in the New IHTSDO IPR (or part thereof) to the extent that it is legally possible to waive these rights.
- 4.4.8 RII shall:
- (a) sign any documents and do all other things as IHTSDO may reasonably request to give effect to the assignment under clause 4.4.5;

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- (b) provide all co-operation, information and assistance reasonably requested by IHTSDO in connection with IHTSDO bringing or defending any claim, action or demand in relation to the New IHTSDO IPR or the Intellectual Property Rights assigned under clause 4.4.5. The reasonable costs for such co-operation, information and assistance shall be paid by IHTSDO (except where both Parties are jointly bringing or defending that claim, action or demand, in which case each Party shall bear its own costs); and
 - (c) procure that each person acting on its behalf under or in connection with this Agreement shall also do the things required of it under this clause 4.4.8.

4.5 **New RII IPR**

4.5.1 IHTSDO grants RII a worldwide, royalty-free licence to:

- (a) incorporate SNOMED CT Allowable Content, and any Spanish language translations of SNOMED CT Allowable Content, into LOINC;
- (b) modify the SNOMED CT Allowable Content, and any Spanish language translations of SNOMED CT Allowable Content, to the extent necessary to adapt the SNOMED CT Allowable Content and Spanish language translations of SNOMED CT Allowable Content to standard LOINC distribution formats; and
- (c) use, load, execute, store, transmit, display, copy, distribute and publish all SNOMED CT Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.5.1(a)-(b) above, incorporated into LOINC in accordance with this Agreement,

provided that any such SNOMED CT Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.5.1(a)-(b) above, may be distributed and published by RII only as an integral part of LOINC (and not as a standalone work).

4.5.2 In performing the Cooperative Work in relation to the Cooperative Areas, the Parties will produce content additions or modifications to LOINC as a result of incorporating the SNOMED CT Allowable Content, including any translations and modifications incorporated pursuant to clauses 4.5.1(a)-4.5.1(b) above (the “**New RII Content**”).

4.5.3 Subject to clause 4.1.1, RII shall own all right, title and interest in and to all Intellectual Property Rights in the New RII Content and any Intellectual Property Rights in the selection, arrangement or compilation of SNOMED CT Allowable Content, or translations thereof, as incorporated within LOINC, the Intellectual Property Rights

referred to in this Clause 4.5.3 being the “**New RII IPR**”. Nothing in this clause 4.5 shall affect IHTSDO’s underlying Intellectual Property Rights in and to SNOMED CT.

4.5.4 IHTSDO shall not, and shall procure that no person acting on its behalf shall, register or attempt to register any of the New RII IPR or any right, title or interest in or to it.

4.5.5 IHTSDO:

(a) assigns to RII (by way of present assignment of future Intellectual Property Rights) all of its right, title and interest in and to the New RII IPR; and

(b) shall procure that each person acting on behalf of IHTSDO under or in connection with this Agreement assigns to IHTSDO all of his or her right, title and interest in and to the New RII IPR on terms that entitle IHTSDO to assign the New RII IPR to RII pursuant to clause 4.5.5(a) above.

4.5.6 In so far as clause 4.5.5 assigns any right, title or interest in or to any Intellectual Property Rights, the assignment shall include all rights and benefits relating to the assigned Intellectual Property Rights, including the right to sue for damages and to claim any other remedy or relief in respect of any infringement or unauthorised use of those Intellectual Property Rights that occurred before the date of the assignment.

4.5.7 IHTSDO shall procure that every author of the New RII IPR (or any part of the New RII IPR) acting on its behalf irrevocably and unconditionally waives all moral rights in the New RII IPR (or part thereof) to the extent that it is legally possible to waive these rights.

4.5.8 IHTSDO shall:

(a) sign any documents and do all other things as RII may reasonably request to give effect to the assignment under clause 4.5.5;

(b) provide all co-operation, information and assistance reasonably requested by RII in connection with RII bringing or defending any claim, action or demand in relation to the New RII IPR or the Intellectual Property Rights assigned under clause 4.5.5. The reasonable costs for such co-operation, information and assistance shall be paid by RII (except where both Parties are jointly bringing or defending that claim, action or demand, in which case each Party shall bear its own costs); and

(c) procure that each person acting on its behalf under or in connection with this Agreement shall also do the things required of it under this clause 4.5.8.

5. PERFORMING THE COOPERATIVE WORKS

- 5.1.1 In performing the Cooperative Work in relation to the Cooperative Areas, the Parties shall produce the Release Files in the manner described in paragraph 6 of Schedule 2, which shall contain Allowable Content.
- 5.1.2 The Parties shall have the responsibilities for the production of the Release Files in the manner described in paragraph 8 of Schedule 2.
- 5.1.3 RII develops coded representations of questionnaires and assessment scales within LOINC, including representations of the specific questions within these instruments. Although the domain of questionnaires and patient assessment instruments falls outside of the current Cooperative Areas, the Parties expect that these items will initially be considered for inclusion in LOINC. However, where answers to these questions fall within domains covered by SNOMED CT, this Agreement permits IHTSDO to assign appropriate SNOMED CT concepts to represent these answers for inclusion in SNOMED CT.

6. TRANSLATIONS

- 6.1.1 RII grants IHTSDO the right to translate any LOINC Allowable Content into Spanish and incorporate such translations into SNOMED CT on the licence terms set out in clause 4.4.1.
- 6.1.2 IHTSDO grants RII the right to translate any SNOMED CT Allowable Content into Spanish and incorporate such translations into LOINC on the licence terms set out in clause 4.5.1
- 6.1.3 The Intellectual Property Rights in and to certain translations of the English language version of SNOMED CT are owned by IHTSDO Members. RII may request a licence to translations of SNOMED CT from IHTSDO, in which case IHTSDO shall formally request the appropriate IHTSDO Member(s) to license their translation of SNOMED CT to RII on appropriate license terms.
- 6.1.4 Each Party shall notify the other Party of any errors it identifies in the other Party's works of nomenclature, or any translation errors brought to its attention, and shall provide any proposed correction to rectify such error.

7. NON-DUPLICATION

7.1 Non-duplication

7.1.1 The Parties shall work together in good faith with the aim that each Party shall not extend the scope of SNOMED CT and LOINC in ways that would result in a duplication of effort, therefore:

(a) RII shall not distribute LOINC Parts in the Cooperative Areas that represent organisms, body parts, or clinical findings (concepts that represent the result of a clinical observation, assessment or judgment) as a standalone work, nor promote the use of LOINC Parts for coding such entities except as a constituent of LOINC Terms;

(i) The Parties agree that a table of Maps of LOINC Parts to another terminology do not constitute a standalone work as contemplated in 7.1.1(a)

(b) RII will only create and distribute LOINC Parts and LOINC Part Hierarchies that organize or are constituents of LOINC Terms, and RII shall provide in their distribution the mappings to equivalent SNOMED CT codes for these LOINC Parts, where such mappings exist, and will encourage the use of these SNOMED CT codes; and

(c) IHTSDO shall not create and distribute new SNOMED CT Concepts that represent orders or observables in the Cooperative Areas, except as specified in paragraph 5.2 of Schedule 2 (such as in response to requests from IHTSDO Members in accordance with the IHTSDO Articles of Association).

8. ENDORSEMENT

8.1 The Parties acknowledge that a key objective of this Agreement is to enable SNOMED CT and LOINC to be used together in ways that benefit the delivery of healthcare through more effective use of electronic information systems. Therefore, both Parties shall encourage appropriate uses of both terminologies without prejudice to their existing obligations to their respective user communities. RII recognises that IHTSDO has an obligation to continue to support IHTSDO Members that do not choose to use LOINC. Likewise, IHTSDO recognises that RII has an obligation to continue to support LOINC users that do not choose to use SNOMED CT.

8.2 In entering into this Agreement, IHTSDO endorses the use of LOINC Codes for representation of orders and observations in countries where LOINC has been adopted.

8.3 IHTSDO and RII both endorse the statement that, LOINC provides codes that represent the names of information items (e.g. questions) and SNOMED CT provides codes that may represent nominal and ordinal values (e.g. answers) for these named information items.

8.4 In entering into this Agreement, the Parties have agreed to minimise the duplication of work, create semantic links between their respective terminologies and cooperate with one another in ways that enable the delivery of consistent guidelines on effective ways to use LOINC and SNOMED CT together.

9. GOVERNANCE AND APPROVALS

9.1 Introduction

9.1.1 The Associate Director of Terminology Services of RII and the Chief Executive Officer (CEO) or the Chair of the Management Board of IHTSDO shall manage the day-to-day operation of this Agreement and may establish ad hoc working groups to undertake projects and resolve issues.

9.2 Executive Policy Group

9.2.1 The Parties shall establish a group (the “**Executive Policy Group**” or “**EPG**”) comprised of three representatives from each Party.

9.2.2 The EPG shall set matters of policy in relation to the development of the relationship between the Parties and shall handle any matters escalated by the Associate Director of Terminology Services of RII and the CEO of IHTSDO.

9.2.3 The EPG shall hold a supervisory role in checking the quality of work carried out under this Agreement and making recommendations where it sees fit.

9.2.4 In the event that the EPG is unable to resolve a dispute within 30 days of referral to it, or such other timescale as agreed by the Parties, the matter shall be referred for mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure.

9.2.5 A chairperson of the EPG (the “**Chair**”) shall be appointed:

- (a) by IHTSDO from the Effective Date for a period of twelve (12) months and every second period of twelve (12) months after that period; and
- (b) by RII for a period of twelve (12) months commencing on the first anniversary of the Effective Date and every second period of twelve (12) months after that period.

9.2.6 No business may be transacted at any meeting of the Executive Policy Group unless a quorum is present. A meeting of the EPG shall be quorate only if all six EPG members are present. In the event that an EPG member is unable to attend a meeting due to exceptional circumstances, then he or she may nominate another EPG member as a proxy to attend the meeting on his or her behalf. An EPG member may also nominate a non-EPG member as a proxy, provided that:

- (a) the proxy has the necessary knowledge and experience to fulfil the role;
- (b) the proxy has been adequately briefed in advance of the meeting; and
- (c) the other Party agrees to the nomination in advance of the meeting.

9.2.7 Each Party shall bear its own costs and expenses incurred through participating in the Executive Policy Group and performing any activities in relation to this Agreement.

10. ANNUAL WORK PLAN PROCESS

10.1 Process

10.1.1 The Parties shall agree, on an annual basis, a plan of the work to be undertaken by the Parties in connection with this Agreement for the following 12 month period taking account of available resources (the “**Work Plan**”).

10.1.2 The Parties shall work together in good faith to develop the Work Plan and shall provide each other with reasonable assistance to produce the Work Plan e.g. technical support and estimates of effort required, elapsed time and budget.

10.1.3 Annual Work Plans shall be submitted to the Executive Policy Group and then to the necessary level of approval within RII and IHTSDO. The Parties shall adhere to any Work Plans which have been approved by both Parties.

10.1.4 The EPG shall develop a process for the creation and management of Work Plans in order to meet requirements identified by the EPG and which aligns with the governance processes of the Parties. The Parties shall work in good faith to incorporate Work Plans developed by the EPG within the overall work plans of their respective organisations.

10.1.5 In the event of unforeseen changes in funding or personnel, one Party may need to revise their obligations under the Work Plan. That Party shall submit the proposed revision to the other Party for discussion and prioritisation, and documentation of an approved deviation from the Work Plan. Either Party may submit the proposed changes to the EPG for review.

11. **TERM OF THE AGREEMENT**

The Term of this Agreement shall commence on the Effective Date and shall continue until either Party terminates this Agreement in accordance with clause 12.

12. **TERMINATION**

12.1 **Termination for Convenience**

Either Party may terminate this Agreement for convenience on three (3) years' written notice, such notice to be issued no sooner than the seventh anniversary of the Effective Date.

12.2 **Termination for Cause**

Either Party may terminate this Agreement by giving written notice to the other Party if:

- 12.2.1 the other Party commits a material breach of this Agreement which is incapable of remedy;
- 12.2.2 the other Party commits a material breach of this Agreement, and fails to remedy that breach within ninety (90) days of receipt of a written notice specifying the breach and requiring that the breach be remedied;
- 12.2.3 the other Party incorporates in any public release of its works of nomenclature (by the IHTSDO as part of a public release of SNOMED CT, and by RII as part of a public release of LOINC) content other than the Allowable Content, in breach of this Agreement, and fails to remove that offending content from the following public release of its work of nomenclature;
- 12.2.4 the other Party is unable or admits inability to pay its debts as they fall due (or is deemed to or declared to be unable to pay its debts under applicable law);
- 12.2.5 the other Party's claims damages under this Agreement which exceed the liability cap set out in clause 14.1;
- 12.2.6 the other Party suspends or ceases to carry on (or threatens to suspend or to cease to carry on) all or a material part of its business; or
- 12.2.7 any action, proceedings, procedure or step is taken in relation to any of the following (or any analogous action, proceedings, procedure or step is taken in any jurisdiction):

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- (a) the suspension of payments, a moratorium of any indebtedness, winding-up, dissolution, administration or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) of the other Party;
 - (b) a composition, compromise, assignment or arrangement by the other Party with or for the benefit of its creditors; or
 - (c) the appointment of a liquidator, receiver, administrator, administrative receiver, compulsory manager or similar officer in respect of the other Party or any of its assets or undertaking.

12.3 **Consequences of Termination**

- 12.3.1 Following termination of this Agreement for any reason, the Parties shall bring the activities carried on under this Agreement to an end in a smooth and orderly manner, and shall seek to minimise any detrimental impact on either Party.
- 12.3.2 Clauses 4 (other than as specified in clause 12.3.3), 12.3.1, 14, 15 and 17 shall survive termination of this Agreement for any reason.
- 12.3.3 The licences granted under clauses 4.2.1, 4.2.3, 4.4.1(a) and 4.5.1(a) shall terminate on the termination of this Agreement.

13. **REPRESENTATIONS AND WARRANTIES**

13.1 **By IHTSDO**

IHTSDO represents and warrants to RII that:

- 13.1.1 it is an association (*foreningen*) validly existing under the laws of Denmark;
- 13.1.2 it has all the requisite power and authority to enter into this Agreement and to perform its obligations under this Agreement; and
- 13.1.3 nothing in this Agreement contravenes or will contravene any provision of the IHTSDO Articles or any of its present or future obligations.

13.2 **By RII**

RII represents and warrants to IHTSDO that:

- 13.2.1 it is a non-profit corporation validly existing under the laws of the state of Indiana, USA;

13.2.2 it has all the requisite power and authority to enter into this Agreement and to perform its obligations under this Agreement; and

13.2.3 nothing in this Agreement contravenes or will contravene any provision of its Articles of Incorporation and Bylaws or any of its present or future obligations.

14. **LIMITATIONS OF LIABILITY**

14.1 **Liability Limit**

Subject to clause 14.3, the entire aggregate liability of each Party under or in connection with this Agreement, whether in contract, tort (including negligence), misrepresentation or otherwise, shall not exceed \$400,000 within any three year period.

14.2 **Liabilities Excluded**

EXCEPT AS OTHERWISE PROVIDED IN CLAUSE 14.1 AND SUBJECT TO CLAUSE 14.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES, INCLUDING ANY DAMAGES FOR BUSINESS INTERRUPTION, LOSS OF USE, DATA, GOODWILL, REVENUE OR PROFIT, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT THE BREACHING PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

14.3 **Liabilities Not Limited or Excluded**

Nothing in this Agreement limits or excludes the liability of either Party:

14.3.1 for fraud (including fraudulent misrepresentation);

14.3.2 resulting from grossly negligent acts or omissions or wilful misconduct of that Party; or

14.3.3 for breach of the obligations contained in clause 4 (*Intellectual Property Rights*) or clause 15 (*Confidentiality*).

15. **CONFIDENTIALITY**

15.1 **Obligations of the Receiving Party**

15.1.1 The Receiving Party shall:

(a) keep the Confidential Information confidential;

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- (b) not disclose the Confidential Information to any person, other than in accordance with this clause 15 (*Confidentiality*), unless it first obtains the written consent of the Disclosing Party; and
 - (c) use the Confidential Information only for the purpose or purposes for which it was disclosed.

15.1.2 Without limiting the generality of clause 15.1.1, the Receiving Party shall:

- (a) not disclose the Confidential Information to or in the presence of any person other than its employees and consultants who need to know the Confidential Information in connection with this Agreement;
- (b) advise those employees and consultants to whom the Confidential Information is to be disclosed of their obligations with respect to the Confidential Information prior to such disclosure and procure their compliance with such obligations; and
- (c) take all action reasonably necessary to secure the Confidential Information against theft, loss and unauthorised disclosure.

15.2 **Excluded Confidential Information**

The obligations in clause 15.1 do not apply to any Confidential Information which:

- 15.2.1 is at the date of this Agreement in, or at any time after the date of this Agreement comes into, the public domain other than through the Receiving Party's breach of this Agreement;
- 15.2.2 can be shown by the Receiving Party to the reasonable satisfaction of the Disclosing Party to have been known by the Receiving Party before disclosure to the Receiving Party;
- 15.2.3 has been developed by the Receiving Party independently, without reference to any information provided by or otherwise obtained from the Disclosing Party; or
- 15.2.4 subsequently comes lawfully into the possession of the Receiving Party from a third party.

15.3 **Permitted Disclosures**

15.3.1 The obligations in clause 15.1 do not prevent a disclosure of Confidential Information:

-
- (a) which is required by applicable law or by order of a court of competent jurisdiction or pursuant to a binding order or direction of a tax or fiscal authority or other regulatory body;
 - (b) to the Receiving Party's professional advisors which is necessary for the purposes of receiving professional advice in relation to this Agreement;
 - (c) by IHTSDO to its Management Board and Executive Team or to any of its Members as represented by their appointed General Assembly representatives; or
 - (d) by RII to its Center for Biomedical Informatics, and Regenstrief Investigators, as appropriate.
- 15.3.2 Nothing in this clause 15 shall prevent either Party from exercising any right under any licence in respect of any Intellectual Property Rights granted under this Agreement. In the event of any conflict between this clause 15 and any such licence, the licence shall prevail.
- 15.3.3 A Party shall not publish information about this Agreement or about the other Party that is inconsistent with or misrepresents the relationship between the Parties as documented herein.
- 15.3.4 Each Party shall be entitled to disclose this Agreement to third parties.

16. MISCELLANEOUS PROVISIONS

16.1 Entire Agreement

- 16.1.1 This Agreement, and any other documents incorporated into this Agreement, constitutes the entire agreement and supersedes any previous agreements between the Parties relating to the subject matter of this Agreement.
- 16.1.2 Each Party acknowledges that it has not relied on or been induced to enter into this Agreement by a representation other than those expressly set out in this Agreement and the agreements and other documents incorporated into this Agreement.
- 16.1.3 A Party is not liable to the other Party for a representation that is not set out in this Agreement or the agreements and other documents incorporated into this Agreement.
- 16.1.4 Clauses 16.1.1 to 16.1.3 do not affect a Party's liability in respect of a fraudulent misrepresentation.

16.2 **Assignment**

- 16.2.1 Subject to clause 16.3, neither Party may assign, transfer or otherwise dispose of any or all of its rights or obligations under this Agreement without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed).
- 16.2.2 Subject to clause 16.3, neither Party may assign, transfer or otherwise dispose of any or all of its right, title or interest in or to any Intellectual Property Rights in the Jointly Owned New Works without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed).

16.3 **Insolvency/Dissolution of a Party**

- 16.3.1 Where a Party is (or believes that it is) at risk of being the subject of any of the events or proceedings in clauses 12.2.3, 12.2.6 or 12.2.7, that Party shall inform the other Party as soon as possible to enable the Parties to discuss how to address the impact of those events or proceedings on this Agreement, the licences and other rights granted under this Agreement and the Intellectual Property Rights created pursuant to this Agreement.
- 16.3.2 In the event that IHTSDO is dissolved with substantially all activities of IHTSDO being transferred to a replacement entity as formally identified by the General Assembly of IHTSDO, IHTSDO's rights and obligations under this Agreement, and its right, title and interest in and to the Intellectual Property Rights in the Jointly Owned New Works, shall transfer automatically to such replacement entity in accordance with the IHTSDO Articles.
- 16.3.3 In the event that RII is dissolved with substantially all activities of RII in relation to LOINC being transferred to a replacement entity, RII's rights and obligations under this Agreement, and its right, title and interest in and to the Intellectual Property Rights in the Jointly Owned New Works, shall transfer automatically to such replacement entity in accordance with RII's memorandum and articles of association.

16.4 **No Waiver**

- 16.4.1 A failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies.
- 16.4.2 No single or partial exercise of a right or remedy provided by this Agreement or by law prevents a further exercise of the right or remedy or the exercise of another right or remedy.

16.4.3 EACH OF THE PARTIES IRREVOCABLY WAIVES ANY AND ALL RIGHTS TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT.

16.5 No Partnership

No provision of this Agreement creates a partnership between the Parties or makes either Party the agent of the other Party for any purpose. Neither Party has any authority to bind, to contract in the name of or to create a liability for the other Party in any way or for any purpose.

16.6 Severability

16.6.1 The provisions contained in each clause of and Schedule to this Agreement are enforceable independently of each other and the validity of this Agreement will not be affected if any clause of or Schedule to this Agreement (or part thereof) is invalid or otherwise unenforceable.

16.6.2 If a clause of or Schedule to this Agreement (or any part thereof) is void, but would be enforceable if any part of the provision were deleted, the provision in question will apply with that deletion, but only to the extent that the meaning of the provision is not altered by that deletion.

16.7 Variation

No variation of this Agreement, including to the Cooperative Areas, shall be effective unless it is in writing and signed by the Parties.

16.8 Rights of Third Parties

A person who is not a party to this Agreement has no right to enforce any of its terms.

16.9 Counterparts

This Agreement may be executed in any number of counterparts, each of which when executed and delivered is an original, but all the counterparts together constitute the same agreement.

16.10 Notices

16.10.1 All notices served by one Party on the other Party under or in connection with this Agreement must be:

- (a) in writing (which for the purposes of this clause 16.10 shall include by email); and

-
- (b) delivered by hand or sent by email, recorded delivery, post or facsimile transmission to the email address, postal address or fax number specified in clause 16.10.4.
- 16.10.2 Notices sent by facsimile transmission must be followed by a copy of the notice sent by recorded delivery post, which shall be dispatched within twenty-four (24) hours of completion of the facsimile transmission.
- 16.10.3 Notices sent by email must be clearly marked in the email subject line or title: “Contract Notice” and must be followed by a copy of the notice sent by recorded delivery post, which shall be dispatched within twenty-four (24) hours.
- 16.10.4 The following email addresses, postal addresses and fax numbers are specified for the purposes of clause 16.10.1(b):
- (a) for notices served on IHTSDO:
- ceo@ihtsdo.org
- The International Health Terminology Standards Development Organisation
IHTSDO, Gammeltorv 4, 1. sal,
DK-1457 Copenhagen K,
Denmark
- Marked for the attention of the Chief Executive Officer
- +45 44 44 87 36; and
- (b) for notices served on RII:
- director@loinc.org
- The Regenstrief Institute, Incorporated
1050 Wishard Blvd., 6th Floor RHC
Indianapolis, IN 46202
USA
- Marked for the attention of Associate Director of Terminology Services
- +1 317-423-5695
- With a copy to
- klooney@regenstrief.org
-

The Regenstrief Institute, Incorporated
1050 Wishard Blvd., 6th Floor RHC
Indianapolis, IN 46202
USA

Marked for the attention of General Counsel.

- 16.10.5 A notice given in accordance with clause 16.10 shall, in the absence of evidence that it was received earlier (in which case it shall be deemed given when actually received), be deemed given as follows:
- (a) if sent by email, when the party to whom the email is sent acknowledges receipt of the email;
 - (b) if delivered by hand, when delivered to the postal address specified in clause 16.10.4;
 - (c) if sent by recorded delivery post:
 - (i) if posted from within the same country as the delivery address, five (5) Business Days after it was posted; or
 - (ii) otherwise, fifteen (15) Business Days after it was posted; and
 - (d) if sent by facsimile transmission, on completion of the transmission.

17. **GOVERNING LAW AND JURISDICTION**

17.1 **Governing Law**

All issues and questions concerning the construction, validity, enforcement and interpretation of this Agreement and the Schedules hereto shall be governed by, and construed in accordance with, the laws of the State of New York, U.S.A. without giving effect to any choice of law or conflict of law rules or provisions that would cause the application of the laws of any jurisdiction other than the State of New York, U.S.A.

17.2 **Jurisdiction**

The Parties irrevocably submit to the exclusive jurisdiction of any state or Federal court sitting in the Manhattan Borough of the City of New York in the State of New York, U.S.A. over any suit, action, claim or proceeding arising out of this Agreement. The Parties irrevocably waive and agree not to assert, by way of motion, as a defence or otherwise, any claim that they are not subject to the jurisdiction of any such court, any objection that they may now or hereafter have to the laying of the venue of any such suit, action, claim or proceeding brought in any such court and any claim that any such suit,

action, claim or proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereby irrevocably consents to service of process given in the manner provided for notices pursuant to clause 16.10.

SCHEDULE I

DEFINITIONS AND INTERPRETATION

1. Defined Terms

1.1 In this Agreement:

“**Allowable Content**” means the LOINC Allowable Content and the SNOMED CT Allowable Content;

“**Business Day**” means any day other than a Saturday, a Sunday or a national, state or federal holiday in Denmark or the USA;

“**Chair**” has the meaning given in clause 9.2.5;

“**Confidential Information**” means all information of a confidential nature that is disclosed (by whatever means, and whether directly or indirectly) by either Party (or any of the disclosing Party’s subcontractors, agents, consultants or employees) to the other Party (or any of the other Party’s subcontractors, agents, consultants or employees) and which relates to the disclosing Party’s business, including any information of a confidential nature relating to the products, operations, processes, plans, intentions, product information, market opportunities or business affairs of the disclosing Party or its contractors, suppliers, customers, clients or other contacts; For information to be considered confidential information under this Agreement, it must be identified as such by the Disclosing Party at the time of disclosure or manifestly of a confidential nature;

“**Cooperative Areas**” has the meaning given in clause 3.1.2;

“**Cooperative Work**” has the meaning given in clause 3.1.1;

“**Disclosing Party**” means the Party making a disclosure of Confidential Information to the other Party (the “**Receiving Party**”);

“**Effective Date**” means the date of this Agreement;

“**Evaluation Procedure**” means a concept which is a subtype of the SNOMED CT concept “evaluation procedure”, which is identified by the SNOMED CT identifier 386053000;

“**Executive Policy Group**” or “**EPG**” has the meaning given in clause 9.2.1;

“**Expression Association**” means a representation of the equivalence or similarity of meaning between codes in another terminology (e.g. LOINC) and a SNOMED CT Expression;

“**IHTSDO Affiliate Licence**” means the standard IHTSDO Affiliate Licence, as amended from time to time;

“**IHTSDO Articles**” means the Articles of Association (*vedtægter*) of IHTSDO;

“**IHTSDO Member**” means a member of IHTSDO pursuant to the IHTSDO Articles;

“**Intellectual Property Rights**” (IPR) means:

- (a) patents, rights in inventions, trade marks and trade and business names (including service marks), design rights, utility models, copyright (including copyright in computer software), database rights and know how (including trade secrets and confidential business information), in each case whether registered or unregistered;
- (b) any rights in any jurisdiction that are similar or analogous to any of the rights described in paragraph (a); and
- (c) any pending applications or rights to apply for registrations of any of the rights described in paragraphs (a) or (b);

“**International Release of SNOMED CT**” means the release produced and distributed by or on behalf of the IHTSDO to all IHTSDO Members and Affiliate Licensees, consisting of the SNOMED CT release files and documentation;

“**LOINC**” means the work of clinical nomenclature called Logical Observation Identifiers Names and Codes (LOINC) that provides a universal code system for identifying laboratory and clinical observations;

“**LOINC Allowable Content**” means each of the following, but only in so far as they relate to the Cooperative Areas and have been included in a public release or approved by RII for distribution to IHTSDO: LOINC Codes, LOINC Fully Specified Names, LOINC Part Codes, LOINC Part Display Names, LOINC Part Hierarchies, LOINC Panel Terms (including their LOINC Names and LOINC Codes but not the structure or content of LOINC Panel Terms), deprecation status and discourage status;

“**LOINC Answer**” means a coded representation of a result value expected from an observation or measurement. Individual LOINC Answers are assigned a non-semantic identifier with a “LA” prefix and a mod-10 check digit;

“**LOINC Code**” means the unique permanent identifier that serves as a computer processable representation of a LOINC Term;

“**LOINC Name**” means the visible display text of a LOINC Term. A LOINC Name provides the human-readable text rendering of its associated LOINC Code. The LOINC Table provides three such LOINC Names: the six-axis fully-specified name, the Long Common Name,

and the Short Name. Each LOINC Name is associated with a LOINC Code. The primary, defining name is the six-axis fully-specified name (LOINC Fully Specified Name);

“LOINC Fully Specified Name” (also known as the Formal Name) means the combined five or six part name of a LOINC Term that includes: the name of the component or analyte measured (e.g., glucose, propranolol), the property observed (e.g., substance concentration, mass, volume), the timing of the measurement (e.g., is it over time or momentary), the type of sample (e.g., urine, serum), the scale of measurement (e.g., qualitative vs. quantitative), and where relevant, the method of the measurement (e.g., radioimmunoassay, immune blot).

“LOINC Panel Term” means a specific kind of LOINC Term that represents a named collection of information with enumerated, discrete contents. For example, the LOINC Term representing a basic metabolic panel containing links to the individual serum measurements of glucose, creatinine, calcium, etc;

“LOINC Part” means a coded representation of a value for a dimension used to specify a LOINC Term. Individual LOINC Parts are assigned a non-semantic identifier with a “LP” prefix and a mod-10 check digit;

“LOINC Part Code” means the unique, permanent, non-semantic identifier that serves as a computer processable representation of a LOINC Part. LOINC Part Codes contain a “LP” prefix and a mod 10 check digit;

“LOINC Part Display Name” means the visible display text of a LOINC Part.

“LOINC Part Type” means the attribute of a LOINC Part identifying the role that this LOINC Part fulfills in relation to the LOINC Term (e.g., the Component, Method, etc);

“LOINC Part Hierarchy” means an ordered classification of LOINC Parts within a given kind of LOINC Part Type;

“LOINC Release” means the release produced and distributed worldwide by the Regenstrief Institute consisting of the LOINC release files and documentation that is governed by the LOINC Copyright Notice and License (available at <http://loinc.org/terms-of-use>);

“LOINC Table” means the primary LOINC release distribution file that is currently available in several formats;

“LOINC Term” means a representation of a question about a clinical phenomenon that can be observed or measured (e.g. “serum sodium concentration”, “measured body height”). LOINC Terms can be used as part of an order for an observation or measurement, or to name items in result reports. LOINC Terms can represent individual measurements or named collections of measurements such as panels or clinical documents;

“**Map**” means a representation of the equivalence or similarity of meaning between a code in one terminology and a code in another terminology;

“**New IHTSDO IPR**” has the meaning given in clause 4.4.3;

“**New RII IPR**” has the meaning given in clause 4.5.3;

“**Jointly Owned New Work**” has the meaning given in clause 4.3.1;

“**nomenclature**” means a system of terms which is elaborated according to pre-established naming rules;

“**Observable Entity**” means a concept which is (or when classified in accordance with the Observables Model would be) a subtype of the SNOMED CT concept “observable entity”, which is identified by the SNOMED CT identifier 363787002;

“**Observables Model**” means the part of the SNOMED CT Concept Model which specifies the permitted relationships of concepts which are subtypes of “Observable entity” and “Evaluation Procedure” with other SNOMED CT Concepts. Like other parts of the SNOMED CT Concept Model, the Observables Model is subject to continuing process of maintenance and includes revisions approved as part of that maintenance process;

“**Release File**” means the files represented in the LOINC Release or International Release of SNOMED CT;

“**SNOMED CT**” means the concept-based work of clinical nomenclature and classification with multiple hierarchies and semantic definitions known as SNOMED Clinical Terms (SNOMED CT);

“**SNOMED CT Allowable Content**” means each of the following but only in so far as they relate to the Cooperative Areas and have been included in a public release or approved by IHTSDO for distribution to RII: SNOMED CT Identifiers, SNOMED CT Preferred Term (display name) for SNOMED CT Concepts in US English and Spanish, fully specified name for SNOMED CT Concepts in US English and active status of SNOMED CT Concepts, but not the hierarchical structure or relationships between SNOMED CT Concepts;

“**SNOMED CT Concept**” means a SNOMED CT component that represents a clinical idea to which a SNOMED CT Identifier has been assigned;

“**SNOMED CT Concept Model**” means the set of rules specified by IHTSDO that determines the logical structure of SNOMED CT Expressions and the permitted sets of relationships between particular types of SNOMED CT Concepts;

“**SNOMED CT Description**” means a SNOMED CT component that represents a human-readable phrase or name (term) associated with a particular SNOMED CT Concept;

“**SNOMED CT Editorial Guidance**” means guidance on creating and modelling new SNOMED CT content published by IHTSDO from time to time;

“**SNOMED CT Expression**” means a structured combination of one or more SNOMED CT Concept Identifiers used to express an instance of a clinical idea. A SNOMED CT Expression is referred to as pre-coordinated if it contains a single concept identifier and post-coordinated if it includes more than one concept identifier;

“**SNOMED CT Identifier**” has the meaning given in the IHTSDO Affiliate Licence;

“**SNOMED CT Preferred Term**” means the term that is deemed to be the most clinically appropriate way of expressing a SNOMED CT Concept in a clinical record. The Preferred Term varies according to language and dialect. For the purposes of this Agreement the Preferred Term refers to the US English Preferred Term unless otherwise specified;

“**SNOMED CT Refset**” means a work consisting of a set of references to SNOMED CT components which may associate additional properties with components that are members of the set and/or which may indicate associations between members of the set or between members of the set and content of another nomenclature, classification or knowledge structure. The uses of Reference sets include identification of subsets of SNOMED CT content, representation of alternative hierarchical structures and cross maps to classifications;

“**subtype**” means a specialization of a concept, sharing all the definitional attributes of the parent concept, with additional defining characteristics;

“**Term of this Agreement**” means the term of this Agreement which is determined by clause 11; and

“**Work Plan**” has the meaning given in clause 10.1.1.

2. Interpretation

2.1 The headings in this Agreement are for ease of reference only, and do not affect the interpretation of this Agreement.

2.2 A reference in this Agreement to a clause or a Schedule is to a clause of, or a Schedule to, this Agreement.

2.3 A reference in this Agreement to a “person” includes any individual, corporation, partnership, firm, joint venture (whether incorporated or not), trust, government or governmental body, authority, agency or unincorporated organisation or association of persons.

2.4 The word “including” in this Agreement shall be read as “including (without limitation)”, and “include” and “includes” shall be read accordingly, irrespective of whether the words “(without limitation)” are used in certain instances and not in others.

SCHEDULE 2

COOPERATIVE WORKS AND METHODS

1. Maps and Expression Associations between SNOMED CT and LOINC

Figure 1 illustrates the proposed set of maps, Expression Associations and content alignments between SNOMED CT and LOINC. Each of the elements shown in this diagram is described in greater detail in the following sub-sections.

The overall objectives of the proposed approach within the Cooperative Areas are:

- 1) LOINC Parts that are used in the Cooperative Areas and SNOMED CT Concepts that are used in the “Observables Model” will be mapped to one another to the extent necessary to enable convergence towards a common semantic foundation.
 - a. LOINC Parts may be added to LOINC where appropriate to address gaps that prevent mapping from SNOMED CT.
 - b. SNOMED CT Concepts may be added to SNOMED CT to address gaps that prevent appropriate use of LOINC Parts within the Observables Model.
- 2) Existing SNOMED CT Concepts that are subtypes of Observable Entity or Evaluation Procedure (and fall with the scope of Cooperative Areas) will be mapped to LOINC Terms.
 - a. LOINC Terms may be added where necessary to address gaps that prevent mapping SNOMED CT Observable Entities and Evaluation Procedures to an appropriate LOINC Term.
 - b. SNOMED CT Observable Entity and Evaluation Procedure concepts will not be routinely added when a LOINC Term has no corresponding concept in SNOMED CT. Paragraph 5.2.1 of this Schedule describes the specific circumstances in which concepts may be added.
- 3) LOINC Terms that are not already represented by SNOMED CT Concepts will be associated with post-coordinated expressions.

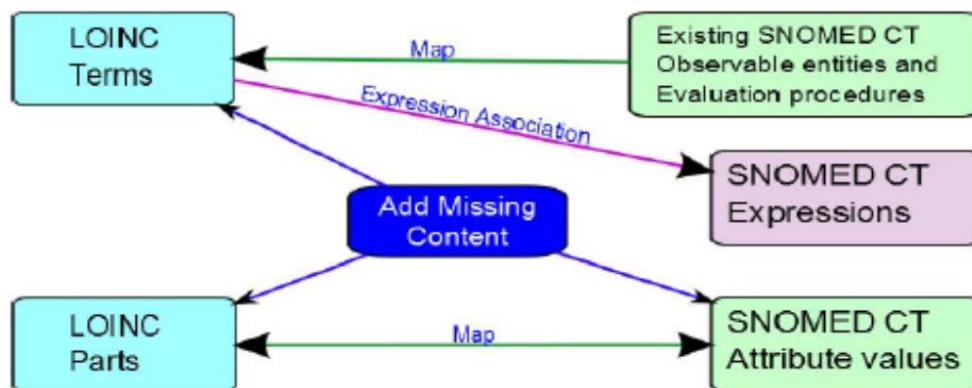


Figure 1. Overview of maps, Expression Associations and content additions that form part of the Cooperative Works

2. Mapping between Existing SNOMED CT Concept and LOINC Terms

Existing SNOMED CT Observable Entity and Evaluation Procedure concepts, that are relevant to the Cooperative Areas, will be mapped to LOINC Terms that have the same meaning.

Rationale

This will avoid a requirement for large scale inactivation of concepts while still providing a bridge to use LOINC Codes in place of SNOMED CT Codes (subject to local jurisdictional policies and requirements).

Extent of mapping

There is no requirement for a complete set of exact maps of all content, or for large scale additions of content to match codes in the other terminology.

Other limitations on mapping:

- Maps will only be considered for SNOMED CT Concepts that are active in the most recent public release of SNOMED CT (at the time when mapping is undertaken).
- Maps will only be created for concepts in SNOMED CT hierarchies that are directly relevant to Cooperative Areas.
- No maps will be created in which the target LOINC Term is marked as "deprecated". LOINC Terms that are marked as discourage may be excluded from the mapping.

Specificity of maps

Each Map will be marked with a value that indicates whether the source and target of the Map are exact matches or whether the source is more or less specific than the target:

-
- An exact one to one map where the meanings are the same;
 - SNOMED CT broader (i.e. LOINC Term is more specific than SNOMED CT concept);
 - SNOMED CT narrower (i.e. LOINC Term is less specific than SNOMED CT concept).

In cases where the SNOMED CT concept is broader, there may be maps to several more specific LOINC Terms.

Content additions resulting from LOINC Term mapping

The intention of SNOMED CT to LOINC Term mapping is to ensure that existing SNOMED CT Concepts in relevant domains are appropriately mapped to LOINC Terms. Therefore, this process is not expected to lead directly to creation of new SNOMED CT Concepts.

Where no LOINC Term provides an exact Map for a SNOMED CT Concept, a new LOINC Term may be added. The case for adding a LOINC Term differs depending on the specificity of the map:

Specificity = "SNOMED CT broader"

- A LOINC Term may be added to match the less specific meaning of the SNOMED CT Concept, if the resulting simplification of the Map has a practical benefit for users.

Specificity = "SNOMED CT narrower"

- A LOINC Term should be added to match the more specific meaning of the SNOMED CT Concept, if this has practical value for order entry or result reporting.

The decision on whether to add a LOINC Term or leave the non-specific Map, depends on assessment of the practical requirements for each case and pursuant to clause 2.3.1.

All additions of LOINC Terms are subject the conditions stated in paragraph 5.1 of this Schedule 2.

3. Mapping between SNOMED CT and LOINC Parts

LOINC Part codes required to support the agreed scope of Cooperative Work will be mapped to SNOMED CT Concepts that have the same meaning.

Additional SNOMED CT Concepts may be added based on LOINC Part codes, where there is no existing equivalent SNOMED CT Concept and where this is required as specified in the extent of mapping paragraph below.

Rationale

These mappings are required to enable representation of LOINC Terms using post-coordinated expressions in SNOMED CT.

Extent of mapping

The set of LOINC Part codes that need to be mapped to SNOMED CT Concepts are those required to enable LOINC Terms to be represented with appropriate SNOMED CT post-coordinated expressions that conform to the revised SNOMED CT Observables Model.

There is no intention to Map all LOINC Parts to SNOMED CT Concepts except as needed to link LOINC Parts used to construct LOINC Terms (in the Cooperative Areas) to the SNOMED CT Concepts needed to represent these LOINC Terms as expressions.

Specificity of maps

Each Map will be marked with a value which indicates whether the source and target of the Map are exact matches or whether the source is more or less specific than the target:

- An exact one to one Map where the meanings are the same;
- SNOMED CT broader (i.e. LOINC Part is more specific than SNOMED CT Concept);
- SNOMED CT narrower (i.e. LOINC Part is less specific than SNOMED CT Concept).

Content additions resulting from LOINC Part mapping

Where an exact Map is not possible due to a gap in one terminology (or due to a difference in the specificity of the terminologies) consideration should be given to addition of content to one or the other terminology.

All additions are subject to the conditions stated in paragraph 5 of this Schedule 2.

4. Expression Associations Between LOINC and SNOMED CT

A LOINC Term that falls within the scope of the Cooperative Work will be associated with a SNOMED CT Expression that represent the same meaning as that LOINC term, using the SNOMED CT Concept model. Each “Expression Association” links the meaning of a LOINC Term to the SNOMED CT semantic model, without requiring the creation of a new SNOMED CT Concept.

The “Expression Association” mechanism will be used in preference to adding “Observable Entity” or “Evaluation Procedure” content to SNOMED CT in the Cooperative Areas.

Some LOINC Terms that cannot be sufficiently defined with the SNOMED CT model may require the addition of a new SNOMED CT Concept mapped to the LOINC Term. Such additions will be limited to those for which there is requirement as defined in paragraph 5.2 of this Schedule 2.

Rationale

Binding between SNOMED CT and LOINC should not depend on creation of a new SNOMED CT Concept where there is no other requirement to create such a concept.

Extent of Expression Associations “Expression Associations” will not be applied to:

- LOINC Terms that are outside the scope of the International Release of SNOMED CT (e.g. a LOINC Term with a meaning that is specific to one country)
- LOINC Terms that are outside the Cooperative Areas
- LOINC Terms that are marked as "deprecated" or deemed to be of insufficient quality, including LOINC Terms with a status of "discourage".

Specificity of associations

Each association will be marked with a value which indicates whether or not the post-coordinated expression represents a “sufficient and necessary” definition of the LOINC Term. If the definition is “sufficient and necessary” then this expression always implies the associated LOINC Term. Otherwise, the expression has a broader meaning than the LOINC Term.

5. Content Addition to SNOMED CT and LOINC

This section specifies:

- The conditions under which SNOMED CT Content within the Cooperative Areas may be used to facilitate matching or related additions to LOINC content; and
- The conditions under which LOINC content within the Cooperative Areas may be used to facilitate matching or related additions to SNOMED CT content.

5.1. Adding LOINC Terms and Parts

5.1.1 LOINC responsive approach to observable requirements

LOINC is free to create new LOINC Terms and Parts, according to its usual business processes, in a responsive way, without waiting for a decision on whether each addition is or could be:

- Included in SNOMED CT with a mapping to LOINC;
- Linked to SNOMED CT using an "Expression Association" (see paragraph 4 of this Schedule 2).

As a result most new LOINC Terms will not be assigned SNOMED CT identifiers and some may not be assigned “Expression Associations”.

Rationale

To retain the practical advantage of LOINC’s responsiveness to user requirements and its ability to include pre-coordinated representations which need not conform to SNOMED CT Editorial Guidance.

5.1.2 Use of SNOMED CT content to create and model LOINC Terms and Parts

Within the scope of this Agreement, RII has permission to use SNOMED CT Content to support creation and modelling of LOINC Terms used to represent orders and/or observations.

Where appropriate new LOINC Parts may be created based on existing SNOMED CT Concepts. Information derived from the source SNOMED CT Concept may be used to populate the LOINC Part. In this case, the derived LOINC Parts must be Mapped to the source SNOMED CT Concepts and the Mapping must be shared with the IHTSDO.

As part of this Agreement, the following items to support this approach are available for distribution by RII as part of the LOINC Release:

- LOINC Part Mappings to SNOMED CT Concepts;
- LOINC Term Associations with SNOMED CT Expressions.

SNOMED CT content included in LOINC Part Mappings and Term Associations with SNOMED CT Expressions may be used by LOINC end-users subject to the terms of the SNOMED CT Affiliate License (www.ihtsdo.org/license.pdf) or a sublicense issued by an IHTSDO Affiliate. Under the terms of the Affiliate License, use of SNOMED CT in countries that are not IHTSDO Members is subject to reporting and fee payment obligations. However, IHTSDO agrees to waive the requirements to report and pay fees for use of SNOMED CT content included in the LOINC Part Mapping and LOINC Term Associations, described in this paragraph 5.1.2, for purposes that support or enable more effective use of LOINC.

Rationale

This sharing of SNOMED CT Content will add value to LOINC content and will encourage convergent modelling and this will reduce duplication of effort.

Greater alignment of LOINC with the SNOMED CT Concept model will enable more effective combined use of SNOMED CT and LOINC.

5.1.3 Use of SNOMED CT content to provide answers to LOINC questions

Where appropriate, LOINC Terms that represent observables with ordinal or nominal answer values should include SNOMED CT Concept names and codes in the LOINC Answer record, and these would be recommended for delivery in messages in countries that are members of IHTSDO.

To support this, IHTSDO will permit distribution of SNOMED CT Concepts in the following ways as part of the specification of LOINC Answers:

- Short lists of less than 50 (fifty) SNOMED CT Concept identifiers and associated preferred terms which provide answers to a specified question.
Note: Longer lists may also be included but only with the explicit written permission of IHTSDO.
- Intensional definition of the set of answers (e.g. all subtypes of the concept "50043002 | respiratory disease |")

Use of these SNOMED CT answers in operational systems will be subject to the terms of the SNOMED CT Affiliate License Agreement (www.ihtsdo.org/license.pdf). A short notice, prepared by IHTSDO, noting the licensing status of these SNOMED CT answers will be included in any material distributed by RII. This will clearly state the conditions for free use of SNOMED CT in Member countries and uses in Non-Member Territories which are chargeable except where special agreements exist (e.g. a public good agreement for coding of new born screening tests).

5.2 Adding SNOMED CT concepts

5.2.1 Addition of new SNOMED CT “Observable Entity” and “Evaluation Procedure” concepts

Within the scope of this Agreement, IHTSDO will not add new SNOMED CT Concepts that are subtypes of “Observable Entity” or “Evaluation Procedure” within the Cooperative Areas, except where one of the following conditions applies:

- a) A specific requirement for such an addition has been formally submitted to the IHTSDO by two or more IHTSDO Members, and the additional concept has been modelled and reviewed in line with SNOMED CT editorial guidelines. Requests for additions derived from lists of LOINC Terms, will not be accepted without special permission from RII.

OR

- b) A LOINC Term cannot be sufficiently specified by a post-coordinated expression based on the SNOMED CT Concept model, and the additional concept has been modelled and reviewed in line with SNOMED CT editorial guidelines. IHTSDO will seek to modify the SNOMED Observable Model to accommodate Observable Entities that measure the sum of 2 or more analyses and other changes to minimize the need to invoke this clause.

In the case of a LOINC Term that represents the name of a panel (or battery) of tests, additional constraints apply. The name of a general type of panel may be added as a SNOMED CT Concept, but the LOINC structure which links a panel name to a specific set of individual observations will not be replicated in SNOMED CT. A SNOMED CT Concept will not be added

to match a LOINC Term for a specific or proprietary panel, instead the LOINC Term shall be mapped to the SNOMED CT Concept representing the appropriate general type of panel. IHTSDO shall also seek to extend the Observables Model to allow post-coordinated expressions to represent classes of panel names that would otherwise require additions of a large number of SNOMED CT Concepts.

Rationale

The intention of these constraints is to minimise duplication of effort on development of coded representations of observables. In addition, the constraints reinforce IHTSDO commitment to cooperation rather than competition with LOINC and thus enable greater openness in sharing of content with a consequent reduction in future duplication of effort.

The ability of IHTSDO to respond to its Members' requirements for additions to the International Release of SNOMED CT is retained but the expectation is that the success of the proposed cooperative approach combined with the revised Observable Model shall limit the demand for additions to SNOMED CT.

Comment

The requirement for pre-coordinated SNOMED CT representations of Observable Entities will be significantly diminished by the new SNOMED CT Observables Model. This model replaces the "interprets" attribute and allows findings related to observables (i.e. findings that are the result of direct observations) to be expressed using the Observables Model (rather than related directly to an Observable Entity concept).

5.2.2 Addition of new SNOMED CT Concepts based on LOINC Parts

Within the scope of this Agreement, the IHTSDO may create new SNOMED CT Concepts based on LOINC Parts if these are required to provide the values for "Observable Entity" attributes.

5.2.3 General conditions for addition of SNOMED CT Concepts based on LOINC content

Subject to the conditions and restrictions in 5.2.1 and 5.2.2, RII shall permit the IHTSDO to create SNOMED CT Concepts that have the same meaning as LOINC Terms or LOINC Parts.

Where additions are permitted:

- SNOMED CT Descriptions (display names) and SNOMED CT defining relationships associated with the new SNOMED CT Concept may be automatically populated from existing LOINC content;
- The resulting SNOMED CT components may be distributed as part of the International Release of SNOMED CT;
- Maps between these new SNOMED CT Concepts and the original LOINC Term or Part shall be created and shall:
 - include an indication that the concept originated from LOINC;

-
- be distributed as part of any release including the added concepts.

The LOINC Terms contained in the International Release of SNOMED CT will be available to end users of SNOMED CT under the standard LOINC Copyright Notice and License (available at <http://loinc.org/terms-of-use>).

Rationale

The ability to add content in this way limits duplication of effort, while allowing convergence towards a common semantic model.

The constraints on additions are intended to minimise duplication of content between SNOMED CT and LOINC within the scope of this Agreement.

6. Distribution of Shared Content in Release Files from each organisation

As portions of this work are completed, IHTSDO and RII shall release information derived from the Cooperative Work as files represented in LOINC or SNOMED CT Release File formats and where mutually agreed, using shared formats.

The set of artefacts resulting from cooperative working will result in the following additions to the Release Files from each organisation:

IHTSDO releases

- a) Map of LOINC Parts to/from SNOMED CT (as a LOINC Map Refset)
- b) Associations of LOINC Terms to SNOMED CT Expressions (as Expression Association Refset)
 - May also include a separate resource of Maps of existing SNOMED CT Observables/Evaluation Procedures → LOINC Terms (as a LOINC Map Refset).
- c) LOINC Answer Map Refset (file format to be defined)
- d) A mutually agreed acknowledgement of the content from LOINC included in SNOMED CT on the IHTSDO web site and in SNOMED CT release notes in perpetuity

LOINC releases

- e) Map of LOINC Part to SNOMED CT Concept ID (as alternative code), for example as currently embedded in RELMA and LOINC web displays
- f) LOINC Term → Expression (format to be determined possibly Expression Association Refset)
- g) LOINC Answers → SNOMED CT Concept ID (possible future Q&A → Expression?)
- h) A mutually agreed acknowledgement of the content from SNOMED CT included in LOINC on the LOINC web site and in LOINC release notes in perpetuity

Schedule of distribution

The two organisations shall release content according to their release schedules.

7. Indication or Origin of Content Included in a Map or Expression Association

The representation of a map or Expression Association between LOINC Term or LOINC Part and a SNOMED CT concept or expression shall contain an indication of the origin of the component prior to the mapping exercise. The indication of origin shall meet the following requirements:

- It shall indicate whether the mapped component originated from LOINC, SNOMED CT or from both terminologies prior to Mapping;
- The indication shall be represented either by a string describing the origin or by a code or integer referring to a string that describes the origin;
- The indication shall be in the same file or physical artefact that represents the Map between a LOINC Code and a SNOMED CT Concept or SNOMED CT Expression.

8. Responsibilities for Production of Cooperative Works

IHTSDO has lead responsibility for associating LOINC Terms with SNOMED “Observable Entity” and “Evaluation Procedure” concepts and/or SNOMED CT post-coordinated expressions, recognizing that a direct mapping from a LOINC Term to a SNOMED CT Observable Entity or Evaluation Procedure can be represented by an association to a SNOMED observable expression containing a single SNOMED CT code for that observation or procedure. This process shall be supported by guidance from and review by LOINC experts.

Mapping between LOINC Parts and SNOMED CT Concepts shall be a shared responsibility of RII and IHTSDO. RII shall provide the list of Parts that are contained in LOINC Terms that are within scope of the cooperation. RII shall also provide existing mappings from these LOINC Parts to SNOMED CT Concepts. IHTSDO shall take lead responsibility for verifying existing mapping, adding SNOMED CT Concepts and maps necessary to complete the Mapping from these LOINC Parts.

RII is responsible for adding new LOINC Terms and LOINC Parts where required under this Agreement.

IHTSDO is responsible for adding new SNOMED CT content where required under this Agreement.

RII is responsible for mapping LOINC Answers to SNOMED CT. This process shall be supported by advice from and review by SNOMED CT experts.

The Parties will establish a process for review and approval of Maps and Expression Associations before they are released publicly.

Mapping may require more than one pass. For some classes of content, an initial step involving direct collaborative work to establish appropriate types of Maps is likely to be required.

SCHEDULE 3

ESSENTIAL ASPECTS OF LOINC AND SNOMED CT

This Schedule 3 provides a simplified introduction to a few aspects of the LOINC and SNOMED CT that need to be understood to make sense of this Agreement.

LOINC

A LOINC Part represents a value for one of six dimensions used to specify a LOINC Term. For example, the tables below show example values for each of the six dimensions of two LOINC Terms. Some LOINC Parts are themselves composed of sub-parts, but the examples below do not illustrate this.

	LOINC Code	LOINC Name	LOINC Code	LOINC Name
LOINC Term	5778-6	Colour of Urine	2951-2	Sodium [Mass or Moles/volume] in Serum or Plasma
Part Type	Part No.	Part Name	Part No.	Part Name
Component	LP28806-5	Colour	LP15099-2	Sodium
Property	LP6886-8	Type	LP6860-3	SCnc [Substance Concentration]
Time	LP6960-1	Pt [Point in time (spot)]	LP6960-1	Pt [Point in time (spot)]
System	LP7681-2	Urine	LP7576-4	Ser/Plas [Serum or Plasma]
Scale	LP7750-5	Nom [Nominal]	LP7753-9	Qn
Method				

The codes used to represent LOINC Terms and LOINC Parts are integers followed by a dash and a single check-digit. In the case of LOINC Parts the numbers are prefixed with LP (standing for LOINC Part).

SNOMED CT

SNOMED CT concepts are arranged in a subtype hierarchy.

Concepts in two SNOMED CT sub-hierarchies have meanings that overlap with the meanings of LOINC Terms. These are:

- Subtypes of **Observable Entity** (363787002). For example, "body height" (50B73000).
- Subtypes of **Evaluation Procedure** (386053000). For example, "measuring height of patient" (14456009).

Concepts in several SNOMED CT sub-hierarchies have meanings that overlap with the meanings of LOINC Parts. For example, some subtypes of **Substance** (105590001), **Organism** (410607006) and **Body Structure** (123037004).

SNOMED CT also includes defining relationships which relate concepts in different hierarchies. These relationships conform to a set of rules referred to as the SNOMED CT **Concept Model**.

The **Observables model** is part of the Concept Model. It specifies the permitted relationships of “Observable entities” and “Evaluation Procedures”. The “Observables model” has similarities with the way LOINC Parts are used to specify LOINC Terms. However, the “Observables model” also specifies relationships between observable entities, Evaluation Procedures and other SNOMED CT concepts, including clinical findings, body structures and organisms. A revised “Observable model” is currently awaiting approval and implementation in SNOMED CT. The revised model is better adapted to supporting the cooperative working proposed by this document. Therefore, references to the “Observable model” in this document refer to the revised model unless otherwise stated.